the White House
President George W. Bush

For Immediate Release
Office of the Press Secretary
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Homeland Security Presidential Directive/HSPD-18

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Subject: Medical Countermeasures against Weapons of Mass Destruction

BACKGROUND

(1) Weapons of Mass Destruction (WMD) -- chemical, biological, radiological, and nuclear agents (CBRN) -- in the possession of hostile states or terrorists represent one of the greatest security challenges facing the United States. An attack utilizing WMD potentially could cause mass casualties, compromise critical infrastructure, adversely affect our economy, and inflict social and psychological damage that could negatively affect the American way of life.

(2) Our *National Strategy to Combat Weapons of Mass Destruction* (December 2002) and *Biodefense for the 21st Century* (April 2004) identify response and recovery as key components of our Nation's ability to manage the consequences of a WMD attack. Our primary goal is to prevent such an attack, but we must be fully prepared to respond to and recover from an attack if one occurs. Accord•ingly, we have made significant investments in our WMD consequence management capabilities in order to mitigate impacts to the public's health, the economy, and our critical infrastructure. The development and acquisition of effective medical counter•measures to mitigate illness, suffering, and death resulting from CBRN agents is central to our consequence management efforts.

(3) It is not presently feasible to develop and stockpile medical countermeasures against every possible threat. The development of vaccines and drugs to prevent or mitigate adverse health effects caused by exposure to biological agents, chemicals, or radiation is a time-consuming and costly process. This directive builds upon the vision and objectives articulated in our *National Strategy to Combat Weapons of Mass Destruction* and *Biodefense for the 21st Century* to ensure that our Nation's medical countermeasure research, development, and acquisition efforts:

(a) Target threats that have potential for catastrophic impact on our public health and are subject to medical mitigation;

(b) Yield a rapidly deployable and flexible capability to address both existing and evolving threats;

(c) Are part of an integrated WMD consequence management approach informed by current risk assessments of threats, vulnerabilities, and capabilities; and

(d) Include the development of effective, feasible, and pragmatic concepts of operation for responding to and recovering from an attack.

(4) In order to address the challenges presented by the diverse CBRN threat spectrum, optimize the investments necessary for medical countermeasures development, and ensure that our activities significantly enhance our domestic and international response and recovery capabilities, our decisions as to the research, development, and acquisition of medical countermeasures will be guided by three overarching principles:

(a) Our preparations will focus on countering current and anticipated threat agents that have the greatest potential for use by state and non-state actors to cause catastrophic public health consequences to the American people.

(b) We will invest in medical countermeasures and public health interventions that have the greatest potential to prevent, treat, and mitigate the consequences of WMD threats.

(c) We will link acquisition of medical countermeasures to the existence of effective deployment strategies that are supportable by the present and foreseeable operational and logistic capabilities of Federal, State, and local assets following a WMD attack or other event that presents a catastrophic public health impact.

(5) Mitigating illness and preventing death are the principal goals of our medical countermeasure efforts. As a class, bio•logical agents offer the greatest opportunity for such medical mitigation, and this directive prioritizes our countermeasure efforts accordingly. This directive also provides for tailoring our Nation's ongoing research and acquisition efforts to continue to yield new countermeasures against CBRN agents and for incorporating such new discoveries into our domestic and international response and recovery planning efforts.

Biological Threats

(6) The biological threat spectrum can be framed in four distinct categories, each of which presents unique challenges and significant opportunities for developing medical countermeasures:

(a) Traditional Agents: Traditional agents are naturally occurring microorganisms or toxin products with the potential to be disseminated to cause mass casualties. Examples of traditional agents include *Bacillus anthracis* (anthrax) and *Yersinia pestis* (plague).

(b) Enhanced Agents: Enhanced agents are traditional agents that have been modified or selected to enhance their ability to harm human populations or circumvent current countermeasures, such as a bacterium that has been modified to resist antibiotic treatment.

(c) Emerging Agents: Emerging agents are previously unrecognized pathogens that might be naturally occurring and present a serious risk to human populations, such as the virus responsible for Severe Acute Respiratory Syndrome (SARS). Tools to detect and treat these agents might not exist or might not be widely available.

(d) Advanced Agents: Advanced agents are novel pathogens or other materials of biological nature that have been artificially engineered in the laboratory to bypass traditional countermeasures or produce a more severe or otherwise enhanced spectrum of disease.

Nuclear and Radiological Threats

(7) Threats posed by fissile and other radiological material will persist. Our Nation must improve its

biodosimetry capabilities and continue to develop medical countermeasures as appropriate to mitigate the health effects of radiation exposure from the following threats:

(a) Improvised Nuclear Devices: Improvised nuclear devices incorporate radioactive materials designed to result in the formation of a nuclear-yield reaction. Such devices can be wholly fabricated or can be created by modifying a nuclear weapon.

(b) Radiological Dispersal Devices: Radiological Dispersal Devices (RDDs) are devices, other than a nuclear explosive device, designed to disseminate radioactive material to cause destruction, damage, or injury.

(c) Intentional Damage or Destruction of a Nuclear Power Plant: Deliberate acts that cause damage to a reactor core and destruction of the containment facility of a nuclear reactor could contaminate a wide geographic area with radioactive material.

Chemical Threats

(8) Existing and new types of chemicals present a range of threats. Development of targeted medical countermeasures might be warranted for materials in the following categories:

(a) Toxic Industrial Materials and Chemicals: Toxic Industrial Materials and Chemicals are toxic substances in solid, liquid, or gaseous form that are used or stored for use for military or commercial purposes.

(b) Traditional Chemical Warfare Agents: Traditional chemical warfare agents encompass the range of blood, blister, choking, and nerve agents historically developed for warfighter use.

(c) Non-traditional Agents: Non-traditional agents (NTAs) are novel chemical threat agents or toxicants requiring adapted countermeasures.

(9) Creating defenses against a finite number of known or anticipated agents is a sound approach for mitigating the most catastrophic CBRN threats; however, we also must simultaneously employ a broad-spectrum "flexible" approach to address other current and future threats. We must be capable of responding to a wide variety of potential challenges, including a novel biological agent that is highly communicable, associated with a high rate of morbidity or mortality, and without known countermeasure at the time of its discovery. Although significant technological, organizational, and procedural challenges will have to be overcome, such a balanced strategic approach would mitigate current and future CBRN threats and benefit public health.

POLICY

(10) It is the policy of the United States to draw upon the considerable potential of the scientific community in the public and private sectors to address our medical countermeasure requirements relating to CBRN threats. Our Nation will use a two•tiered approach for development and acquisition of medical countermeasures, which will balance the immediate need to provide a capability to mitigate the most catastrophic of the current CBRN threats with long-term requirements to develop more flexible, broader spectrum countermeasures to address future threats. Our approach also will support regulatory decisions and will permit us to address the broadest range of current and future CBRN threats.

Tier I: Focused Development of Agent-Specific Medical Countermeasures

(11) The first tier uses existing, proven approaches for developing medical countermeasures to address challenges posed by select current and anticipated threats, such as traditional CBRN agents. Recognizing that as threats change our counter•measures might become less effective, we will invest in an integrated and multi-layered defense. Department-level strategies and implementation plans will reflect the following three guiding principles and objectives:

(a) Evaluate and clearly define investments in near- and mid•term defenses: We will develop and use risk assessment processes that integrate data and threat assessments from the life science, consequence management, public health, law enforcement, and intelligence communities to guide investment priorities for current and anticipated threats. We will openly identify the high-risk threats that hold potential for catastrophic consequences to civilian populations and warrant development of targeted countermeasures.

(b) Target medical countermeasure strategies to satisfy practical operational requirements: We will model the potential impact of high-risk threats and develop scenario-based concepts of operations for medical consequence management and public health mitigation and treatment of a large-scale attack on our population. These concepts of operations will guide complementary decisions regarding medical countermeasure development and acquisition.

(c) Take advantage of opportunities to buttress U.S. defenses: We will coordinate interagency efforts to identify and evaluate vulnerabilities in our current arsenal of countermeasures to protect the U.S. population. Where appropriate, we will target the development of alternate or supplementary medical countermeasures to ensure that a multi-layered defense against the most significant high-impact CBRN threats is established.

Tier II: Development of a Flexible Capability for New Medical Countermeasures

(12) Second tier activities will emphasize the need to capitalize upon the development of emerging and future technologies that will enhance our ability to respond flexibly to anticipated, emerging, and future CBRN threats. Importantly, this end-state will foster innovations in medical technologies that will provide broad public health benefit. Department-level strategic and implementation plans will reflect the following guiding principles and objectives:

(a) Integrate fundamental discovery and medical development to realize novel medical countermeasure capabilities: We will target some investments to support the develop•ment of broad spectrum approaches to surveillance, diagnostics, prophylactics, and therapeutics that utilize platform technologies. This will require targeted, balanced, and sustained investments between fundamental research to discover new technologies and applied research for technology development to deliver new medical capabilities and counter•measures. Although by no means all-inclusive, our goals could include identification and use of early markers for exposure, greater understanding of host responses to target therapeutics, and development of integrated technologies for rapid production of new countermeasures.

(b) Establish a favorable environment for evaluating new approaches: We must ensure that our investments lead to products that expand the scientific data base, increase the efficiency with which safety and efficacy can be evaluated, and improve the rate at which products under Investigational New Drug or Investigational Device Exemption status progress through the regulatory or approval process. In addition, we must continue to use new tools to evaluate and utilize promising candi•dates in a time of crisis. Examples of such tools include the "Animal Rule" for testing the efficacy of medical countermeasures against threat agents when human trials are not ethically feasible and the Emergency Use Authorization. Although by no means all-inclusive, our desired end-state could include the use of novel approaches for improved evaluation tools, streamlined clinical trials that meet safety and regulatory needs, and the development and use of novel approaches to manufacturing.

(c) Integrate the products of new and traditional approaches: We must address the challenges that will arise from inte•grating these new approaches with existing processes. We must incorporate the use of non-pharmacological inter•ventions in our response planning. This integration will forge a flexible biodefense capability that aligns our national requirements for medical countermeasures with the concepts of operation that are used in conjunction with other strategies for mitigating the public health impacts of WMD attacks.

(13) In order to achieve our Tier I and II objectives, it will be necessary to facilitate the development of products and technologies that show promise but are not yet eligible for procurement through BioShield or the Strategic National Stockpile.

We will support the advanced development of these products through targeted investments across a broad portfolio, with the under•standing that some of these products may be deemed unsuitable for further investment as additional data becomes available, but the expectation that others will become candidates for procurement.

POLICY ACTIONS

(14) We will employ an integrated approach to WMD medical countermeasure development that draws upon the expertise of the public health, life science, defense, homeland security, intelligence, first responder, and law enforcement communities, as well as the private sector, to promote a seamless integration throughout the product development life cycle.

(a) The Secretary of Health and Human Services (Secretary) will lead Federal Government efforts to research, develop, evaluate, and acquire public health emergency medical countermeasures to prevent or mitigate the health effects of CBRN threats facing the U.S. civilian population. The Department of Health and Human Services (HHS) will lead the interagency process and strategic planning and will manage programs supporting medical countermeasures development and acquisition for domestic preparedness.

(i) Stewardship. Not later than 60 days after the date of this directive, the Secretary shall establish an interagency committee to provide advice in setting medical countermeasure requirements and coordinate HHS research, development, and procurement activities. The committee will include representatives desig•nated by the Secretaries of Defense and Homeland Security and the heads of other appropriate executive departments and agencies. This committee will serve as the primary conduit for communication among entities involved in medical countermeasure development. The chair of the committee shall keep the joint Homeland Security Council/National Security Council Biodefense Policy Coordination Committee apprised of HHS efforts to integrate investment strategies and the Federal Government's progress in the development and acquisition of medical countermeasures.

(ii) Strategic Planning. Not later than 60 days after the date of this directive, the Secretary shall establish a dedicated strategic planning activity to integrate risk-based require•ments across the threat spectrum and over the full range of research, early-, mid-, and late-stage development, acquisition, deployment, and life-cycle management of medical countermeasures. The Secretary shall align all relevant HHS programs and functions to support this strategic planning.

(iii) Execution. The Secretary shall ensure that the efforts of component agencies, centers and institutes are coordinated and targeted to facilitate both development of near-term medical countermeasures and transformation of our capability to address future challenges. The Secretary shall also establish an advanced development portfolio that targets investments in promising countermeasures and technologies that are beyond early development, but not yet ready for acquisition consideration. In order to realize the full potential for broad partnership with academia and industry, the Secretary shall ensure that HHS coordinates strategies and implementation plans in a manner that conveys integrated priorities, activities, and objectives across the spectrum of relevant Federal participants.

(iv) Engaging the Private Sector and Nongovernmental Entities. The Secretary shall develop and implement a strategy to engage the unique expertise and

capabilities of the private sector in developing medical countermeasures to combat WMD, and shall provide clear and timely communication of HHS priorities and objectives. The Secretary shall consider creating an advisory committee composed of leading experts from academia and the biotech and pharmaceutical industries to provide insight on barriers to progress and help identify promising innovations and solutions to problems such as life-cycle management of medical countermeasures. The Secretary shall designate one office within HHS as the principal liaison for nongovernmental entities who wish to bring new technologies, approaches, or potential medical countermeasures to the attention of the Federal Government.

(b) The Secretary of Defense shall retain exclusive responsibility for research, development, acquisition, and deployment of medical countermeasures to prevent or mitigate the health effects of WMD threats and naturally occurring threats to the Armed Forces and shall continue to direct strategic planning for and oversight of programs to support medical countermeasures development and acquisition for our Armed Forces personnel. The Secretaries of Health and Human Services and Defense shall ensure that the efforts of the Department of Defense (DOD) and HHS are coordinated to promote synergy, minimize redundancy, and, to the extent feasible, use common requirements for medical countermeasure develop•ment. The Secretary of Defense shall ensure that DOD continues to draw upon its longstanding investment and experience in WMD medical countermeasure research, develop•ment, acquisition, and deployment to ensure protection of the Armed Forces, but also to accelerate and improve the overall national effort, consistent with Departmental authorities and responsibilities, and shall ensure that DOD continues to place a special focus on medical countermeasure development for CBRN threat agents because of the unique facilities, testing capabilities, and trained and experienced personnel within the Department. These efforts will constitute the basis for interagency partnership and combined investment to safeguard the American people.

(c) The Secretary of Homeland Security shall develop a strategic, integrated all-CBRN risk assessment that integrates the findings of the intelligence and law enforcement communi•ties with input from the scientific, medical, and public health communities. Not later than June 1, 2008, the Secretary of Homeland Security shall submit a report to the President through the Assistant to the President for Homeland Security and Counterterrorism, which shall summarize the key findings of this assessment, and shall update those findings when appropriate, but not less frequently than every 2 years. The Department of Homeland Security shall continue to issue Material Threat

Determinations for those CBRN agents that pose a material threat to national security.

(d) The Secretaries of Health and Human Services, Defense, and Homeland Security shall ensure the availability of the infrastructure required to test and evaluate medical countermeasures for CBRN threat agents.

(i) The Secretaries of Health and Human Services, Defense, and Veterans Affairs shall leverage their partnership to identify and accelerate research, development, testing, and evaluation programs for the acquisition of medical countermeasures for CBRN threats.

(ii) The Secretary of Health and Human Services and the Secretary of Homeland Security shall develop effective and streamlined processes, including mutually agreed-upon timelines, to assist the respective Secretaries in jointly recommending that the Special Reserve Fund (SRF) be used for the acquisition of specified security countermeasures.

(iii) The Director of National Intelligence shall facilitate coordination across the intelligence community and, in coordination with the Attorney General, engage the law enforcement community to provide all relevant and appropriate WMD-related intelligence information to DHS for the development of the integrated CBRN risk

assessment that is used in prioritizing the development, acquisition, and maintenance of medical countermeasures.

GENERAL

(15) This directive:

(a) shall be implemented consistent with applicable law and the authorities of executive departments and agencies, or heads of such departments and agencies, vested by law, and subject to the availability of appropriations;

(b) shall not be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, and legislative proposals; and

(c) is not intended to, and does not, create any rights or benefits, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, instrumentalities, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

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Source: The White House